Drugs

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How many drugs do we need?

Restricted drug formularies used in the United States of America and in European countries may give some indication as to the minimum number of drugs compatible with maintaining the level of health care currently available in industrialized countries. Most conditions encountered in general practice and in hospitals can probably be managed with about 500 drugs and 1000 dosage forms and strengths, but additional drugs may be advantageous for patients with unusual combinations of disease features and for the treatment of rare conditions.

The World Health Organization's action programme that resulted in a list of 200–250 "essential drugs", including vaccines, salts, nutrients, and vitamins *(1, 2)*, is having a palpable impact on drug prescribing and availability in many Third World countries *(3–5)*. The reduction of expenditure on drugs of doubtful value and on new and expensive products has important economic implications, not only for the countries concerned but also for the drug industry. The possibility that similar restrictive drug policies could be introduced in more affluent communities has triggered harsh reactions in some quarters *(6)*.

Consumer organizations advocate the use of fewer drugs *(5)*, and they are supported by many leading professionals *(7)*. Others are worried that the essential drugs list may be used inappropriately by politicians and health authorities in countries that can afford to spend considerable sums of money on expensive modern drugs *(8)*. The concern of those who look for bad omens is sustained by the appearance of the negative and misleading term "nonessential drugs" for products that do not qualify for the WHO list *(6)*.

While defining a core of indispensable drugs is relatively simple, it is difficult to assess which drugs are useful and should be made available under health care systems in developed countries without serious economic restraints. Some recent attempts to define limited drug formularies in industrialized countries are reviewed below.

United States

Pharmacy and therapeutics committees were set up to devise restricted drug formularies at the New York Hospital in the early 1930s

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(9). Formularies were later introduced in most of the country's major hospitals.

The items included in the formularies of 52 hospitals, including 44 institutions affiliated to universities, were analysed by Rucker & Visconti *(10)*: in 1976 the mean number of drug entities exclusive of different dosage forms and strengths was 641. The lowest number of drugs in a hospital formulary was 380 and the highest was 1329. Teaching centres had fewer approved drugs than did nonacademic hospitals. Approximately 30% of the drugs were combination products, and an average formulary comprised about 450 single drugs.

United Kingdom

Several reports of independent selection efforts in the United Kingdom have appeared during the last decade. A group of general practitioners in London managed to limit prescribing to 245 drugs by a continuous evaluation and selection procedure *(11)*. A similar initiative in Newcastle defined 137–145 drugs that were presumed to cover 90% of the conditions treated in general practice *(12)*.

A joint drug and therapeutics committee of several hospitals in the Wandsworth area of London has been functioning since 1971 *(13)*; its formulary, which has now been adopted for use in two neighbouring districts, contains approximately 2000 drugs, dosage forms and strengths out of approximately 18 000 products available in this country.

The much-debated limited list of drugs for prescription under the National Health Service comprises only a few therapeutic groups *(14)*. The spectrum of drugs available within these categories is rather wide, and it is therefore unlikely that the result of this government initiative can be used to establish the size of a minimum selection.

Italy

A working group of the National Commission of General Practitioners and Clinical Pharmacologists from the Lombardy Regional Centre for Drug Information was set up in 1977 in order to prepare a list of drugs to be recommended for outpatient practice *(15)*. The resulting formulary contained 400 drugs, of which 352 were considered of documented therapeutic efficacy and 34 of doubtful value.

As well as being a medical matter, drug selection has economic, ethical and political dimensions.

Scandinavian countries

The number of drugs marketed in Denmark, Finland, Norway, and Sweden is lower than in most other European countries. The situation in Norway is unique since a prerequisite for registration is a documented need or medical justification *(16)*. No such clause is included in the Swedish regulations, which nevertheless require more than evidence of safety and efficacy for drugs to be approved: products must in addition be shown to be "medically suitable" *(17)*.

Drug and therapeutics committees are now functioning in most hospitals, and in Sweden there have also been a number of regional initiatives. None of the selection programmes have covered all therapeutic areas. However, due to the "need clause" and other features of the national

regulations in Norway, this country's selection of approved products comes closer to a comprehensive limited drug list than do most national formularies *(16)*. Marketing approvals in Norway are reviewed every five years. After the introduction of new and safer drugs, products considered obsolete have been banned.

At present about 1900 dosage forms and strengths representing approximately 800 specific chemical entities and 1100 brand names are on the market. Since the "need clause" has been leniently applied, allowing the marketing of some drugs that do the same job as others already on the market, and of different brands containing the same active principle, not all the products available are strictly necessary from a medical point of view. There is a plethora of neuroleptics, diuretics and antihistamines. Between three and six different brands of some important chemical entities with expired patent rights are marketed (e.g., phenoxymethyl penicillin and theophylline), but most of the commercially less successful products are each supplied by only one manufacturer.

The danger exists that a limited list may be used by some authorities as an excuse to reduce costs in the drug sector even where this is not imperative.

Some useful drugs are not registered and can only be obtained for individual patients through a special licensing procedure. The pharmaceutical firms are apparently reluctant to go through a tedious approval process in this small country if the drugs are not for major diseases and are not expected to take a significant share of the market. The use of nonregistered pharmaceutical products accounts for up to about 20% of the total expenditure on drugs in some large regional hospitals with a wide range of specialized units.

When considering the spectrum of marketed drugs one should also keep in mind that some diseases common in the Third World, for example most parasitic infections, are not a health problem in the Scandinavian countries. Nonregistered medicines for treatment of occasional cases of imported infections must nevertheless be counted among the necessary drugs.

The optimum number of important drugs for an advanced health care system clearly cannot be obtained directly from the Norwegian national formulary. As explained above, some products permitted in Norway do not qualify for inclusion on a limited list, but on the other hand quite a few additions need to be made.

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The limited selections for general practice do not include drugs used to treat critically ill hospitalized patients. Not all remedies required to treat ambulatory patients are necessarily included in hospital formularies. Outpatient and hospital formularies are therefore to some extent supplementary, and so are the ranges of drugs cherished and used by individual general practitioners and specialists who take care of different patient categories.

Although there is considerable latitude in the interpretation of the published reports, it appears that in the more affluent societies substantially more than 200–250 drugs are considered essential by medical experts. The overall impression given by published data and the Norwegian situation is that at least 500 specific chemical entities and 1000 dosage forms and strengths should be available for high-quality health care in

industrialized countries. In fact, the number could be substantially higher since there are probably combinations of circumstances and disease features representing therapeutic niches for additional pharmacological agents. No reasonably sized group of professionals on a drug and therapeutics committee will possess the knowledge and imagination to anticipate which medicines will be most suitable for treating every future patient. Restrictive policies may therefore deprive some patients of optimal treatment unless mechanisms are established to obtain drugs that are not in the formulary.

As well as being a medical matter, drug selection has economic, ethical and political dimensions. From a medical point of view the most important thing is to secure a sufficiently wide range of drugs to provide good health care for all patients. However, economic and political restraints may force medical experts to select only the most cost-effective remedies that can be used to treat common diseases.

The elimination of ineffective, dangerous and overpriced medicines, and irrational combination products, is commendable everywhere. So is the definition of a small common core of indispensable drugs, provided that no one is led to believe that only these are needed for high-quality health care. WHO has been careful to emphasize that the exclusion from its essential list of a drug does not necessarily imply that it is of no value. However, if a limited list is misinterpreted or if the criteria for selection are forgotten or intentionally swept under the carpet for political reasons, the danger exists that it may be used by some authorities as an excuse to reduce costs in the drug sector even where this is not imperative.

Rather than laying down a maximum number of drugs, one should encourage the evaluation and ranking of products with regard to their therapeutic value for each indication. Such evaluation could serve as a guide to the prescribing doctor, and, together with morbidity statistics and costs, help national boards and drug and therapeutics committees to select which drugs should be given priority under conditions of severe, moderate or slight economic restraint. □

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